DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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April 22, 2015

L&K Biomed Company, Limited
Ms. Yerim An
#201, 202 16-25, Dongbaekjungang-ro 16 beon-gil
Giheung-gu, Yongin-si
Gyeonggi-do, 446-916
Republic of Korea

Re: K143363
Trade/Device Name: LnK Spinal Fixation System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, MNH, MNI, KWP, KWQ
Dated: March 19, 2015
Received: March 23, 2015

Dear Ms. An:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143363

Device Name
LnK Spinal Fixation System

Indications for Use *(Describe)*
LnK Spinal Fixation System is non-cervical spinal fixation devices intended for use as posterior pedicle screw fixation system T1-S2/ilium), or as an anterolateral fixation system (T8-L5). All components in the system are limited to skeletally mature patients. These devices are indicated as an adjunct to fusion for all of the following indications regardless of the intended use: degenerative dis disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; stenosis; and failed previous fusion (pseudoarthrosis).

The LnK Spinal Fixation System is a pedicle screw system indicated for the treatment of severe spondylolisthesis (Grades 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion.

In addition, the LnK Spinal Fixation System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine: degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudoarthrosis).

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) SUMMARY

The following 510(k) summary is being submitted as required by 21 CFR 807.92(a):

1. Submitter:

Gook Jin Kang
L&K BIOMED Co., Ltd.
#201, 202 16-25, Dongbaekjungang-ro 16 beon-gil
Giheung-gu, Yongin-si, Gyeonggi-do, 446-916,
Korea
Phone. 82-2-6717-1985
FAX .82-2-6717-1989

Contact Person: Yerim An

Date prepared: March 19, 2015

2. Device Identification

Trade Name	LnK Spinal Fixation System
Common Name	Spinal Fixation Appliances
Product Code	NKB, KWP, KWQ, MNH, MNI
Classification Name	Class III Spinal Interlaminal Fixation Orthosis, 21 CFR §888.3050 Pedicle Screw Spinal System, 21 CFR §888.3070

3. Predicate or legally marketed devices which are substantially equivalent

1) **Primary- L&K Biomed:** VENUS Spinal System K120270
2) **Additional- Stryker**: Xia 3 Spinal System K071373(T), K083393 (T),K091291 (S)

4. Description of the Device

This system is comprised of screws, set screws, rods, crosslink, **Hook** and connectors. The components of this system are manufactured by Titanium alloy (Titanium-6Aluminum-4Vanadium ELI, per ASTM F136) and CoCrMo alloy (Cobalt-28Chromium-6Molybdenum, per ASTM F1537). The screws are available from 4.0 to 8.5mm diameters with lengths ranging from 20-150mm. The purpose of this submission is to add Hooks to this system.

5. Indications for Use

LnK Spinal Fixation System is non-cervical spinal fixation devices intended for use as posterior pedicle screw fixation systems (T1-S2/ilium), or as an anterolateral fixation system (T8-L5). All components in the system are limited to skeletally mature patients. These devices are indicated as an adjunct to fusion for all of the following indications regardless of the intended use:

- degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies);
- spondylolisthesis;
- trauma (i.e., fracture or dislocation);
- deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis);
- tumor;
- stenosis, and
- failed previous fusion (pseudoarthrosis)

The LnK Spinal Fixation System is a pedicle screw system indicated for the treatment of severe spondylolisthesis (Grade 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion.

In addition, the LnK Spinal Fixation System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine: degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor and failed previous fusion (pseudoarthrosis).The pedicle screws are limited to placement in T1-T3 in treating thoracic conditions only. The pedicle screws are not intended to be placed in or treat conditions involving the cervical spine.

6. Comparison of the technology characteristics of the device to predicate and legally marketed devices

Submitter	L&K BIOMED	Stryker
Device Name	LnK Spinal Fixation system	Xia 3 Spinal System
510K #		K071373(T), K083393 (T),K091291 (S)
Regulation Number	21 CFR 888.3050, 21 CFR 888.3060, 21 CFR 888.3070	21 CFR 888.3050, 21 CFR 888.3060, 21 CFR 888.3070
Class	III	III
Product Code	MNI,MNH,KWQ,KWP,NKB	MNI,MNH,KWQ,KWP,NKB
Material	ASTM F136, ASTM F1537	ASTM F136, ASTM F1537
Sterility	Non-sterile	Non-sterile
Rod	Dia: 5.0/5.5/6.0mm Length:40~600mm	Dia:5.5 mm Length:30-600mm
Screw	Dia:4.0~8.5mm Length:20-150mm	Dia 4.0.-10.5mm Length: 20-100mm
Hooks	Ramped Hook - 6.0 Rod(Narrow, Standard, Wide) General Hook - 6.0 Rod(Narrow, Standard, Wide) Pedicle Hook - 6.0 Rod(Narrow, Standard, Wide) Angled Hook - 6.0 Rod(Right, Left) Offset Hook - 6.0 Rod(Right, Left)	Laminar Hook (Small Medium Large, Extended Body, Offset), (Narrow Blade, Standard Blade) Thoracic Laminar Hook (Small Medium Large, Extended Body, Offset) Offset Hook (Right, Left) Pedicle Hook (Small, Medium, Large) Transverse Process Hook (Right, Left)
Indication	LnK Spinal Fixation System is non-	The Stryker Spine XIA® 3 Spinal System is intended for use in the

	cervical spinal fixation devices intended for use as posterior pedicle screw fixation systems (T1-S2/ilium), or as an anterolateral fixation system (T8-L5). All components in the system are limited to skeletally mature patients. These devices are indicated as an adjunct to fusion for all of the following indications regardless of the intended use: *degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies); *spondylolisthesis; *trauma (i.e., fracture or dislocation); *deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis); *tumor; *stenosis, and *failed previous fusion (pseudoarthrosis) The LnK Spinal Fixation System is a pedicle screw system indicated for the treatment of severe Spondylolisthesis (Grade 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion. In addition, the LnK Spinal Fixation System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine: degenerative Spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor and failed previous fusion (pseudarthrosis).	**noncervical spine. When used as an anterior/anterolateral and posterior**, **noncervical pedicle and non-pedicle fixation system**, the XIA® 3 Spinal System is intended to provide additional support during fusion using autograft or allograft in skeletally mature patients in the treatment of the following acute and chronic instabilities or deformities: * Degenerative disc disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); *Spondylolisthesis; * Trauma (i.e., fracture or dislocation); * Spinal Stenosis; * Curvatures (i.e., scoliosis, kyphosis, and/or lordosis); * Tumor; * Pseudoarthrosis; and * Failed previous fusion. The 5.5 mm titanium and Vitallium® rods from the Stryker Spine Radius® Spinal System and6.0 mm Vitallium® rods from XIA Spinal System are intended to be used with the other components of XIA® 3 Spinal System.

The LnK Spinal Fixation System shares technological characteristics similar to the predicate devices. These characteristics include similar design, the same materials, substantially equivalent performance characteristics and the same intended use.

7. Performance Data

Non-Clinical Performance and Conclusions:
Bench testing results demonstrate that LnK Spinal Fixation system performs equivalently to the predicates in static compression bending, static tension, static torsion, dynamic compression bending (in accordance with ASTM F1717-10) and gripping-push down (in accordance with ASTM F1798).
Clinical Performance and Conclusions:
Clinical data and conclusions were not needed for this device.

8. Conclusion

The LnK Spinal Fixation System is substantially equivalent to the predicate device referenced above.